K071245

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by §807.92

Device Name – as required by 807.92(a)(2): AUG - 2 2007

Trade Names:	**TALON® and REVERE®**
Common/Classification Name:	**Denture resin, relining, repairing or rebasing resin**
Classification Regulation:	**872.3760**
Device Class:	Class II
Product Code (Procode):	**EBI**

Premarket Notification submitter:

Company Name:	**Talon Acrylics, Inc.**
Company Address:	**850 N. E. 102nd Ave., Portland, OR 97220**
Contact:	**Sherman Watson, President**
Preparation Date:	April 27, 2007

A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)

Two (2) of the legally marketed predicate devices identified by the submitter are the presently marketed **Comfor-dent Denture Liner, K910795**, and **Comfort Acrylics Pliable Denture Liners and Splints, K900799**, both devices also manufactured by **Comfort Acrylics Company** (now "Inc.), 2103 NE 272nd Ave, Camas, WA. Both predicate devices are listed as "Resin, Denture, Relining, Repairing, Rebasing," devices, regulation number "872.3760," and Product Code "EBI," for which **Comfort Acrylics, Inc.** is Licensed to Manufacture and Distribute for Sale, **TALON®** Thermoplastic composition via Licensing Agreement through **Sherman L. Watson / Talon Acrylics, Inc.**

B. DEVICE DESCRIPTION – as required by 807.92(a)(4)

The submitted devices, **TALON® and REVERE** are a thermoplastic moldable acrylic compound for use in the fabrication, repair and relining of complete and/or partial dentures, dental appliances, and dental prostheses devices, including gaskets for over dentures, splints, night guards and sleep apnea anti-snore devices, and other appliances as prescribed.

The main characteristics of the submitted devices includes:

1. A thermoplastic moldable acrylic
2. Used for fabrication, repair and relining of complete and/or partial dentures, dental appliances and dental prostheses devices to include all the above.
3. Excellent bond to methacrylates

4. Premixed for immediate use and safety
5. Repairable
6. Two (2) hour curing time at 155°F
7. Will not leach out plasticizers into the oral cavity
8. Can be processed in the ½ denture flask method
9. Can be laminated without the use of adhesives or bonding agents
10. Has a "memory" and will not warp under normal wear and handling procedures
11. Gas chromatographic studies verify a residual monomer level of up to 0.14%
12. Shore-D hardness testing shows it will not harden over time under normal wear and handling conditions
13. Eliminates undercut wax-out
14. No need to survey model
15. Not necessary to duplicate models

C. DEVICE CLAIMS - as required by 807.92(a)(4)

TALON® and **REVERE®** are a thermoplastic moldable acrylic compound for use in the fabrication, repair and relining of complete and/or partial dentures, dental appliances, and dental prostheses devices, including gaskets for over dentures, splints, night guards and sleep apnea anti-snore device appliances as prescribed.

D. PRODUCT AND TECHNICAL SPECIFICATIONS - as required by 807.92(a)(4)

TALON® and **REVERE®** thermoplastic moldable acrylic compounds are the same predicate devices as **Comfor-dent Denture, K910795** and **Comfort Acrylics Pliable Denture Liners and Splints, K900799.**

The manufacturer of **TALON®** and **REVERE®** is registered with the FDA and has implemented a Quality System which includes Manufacturing Process Validation Records, Equipment Validation Records, Specification Records, Acceptance Criteria Records, Work Instructions, and Finished Device Acceptance Reports or Records on file, to include Monomer, Polymer, Colorants, Purchasing/Manufacturing, Labeling, Packaging, and Shipping.

E. INTENDED USE - as required by 807.92(a)(5)

TALON® and **REVERE®** are thermoplastic moldable acrylic compounds used by dental professionals for the fabrication, repair and relining of complete and/or partial dentures, dental appliances and dental prostheses devices including TMJ/D Splint Appliances, Night Guards, Sleep Apnea Anti-Snore, Appliances, Athletic Mouth Guards, Fluoride Trays, Repositioning Stints, and other moldable appliances as prescribed. The REVERE® device is the same thermoplastic moldable acrylic compound with the addition of a customer requested coloring agent from a list of Talon Acrylic's agents intended for use in dental appliances and prostheses.

F. INDICATIONS FOR USE

TALON® and **REVERE®** are a moldable acrylic compound for use in the fabrication, repair and relining of complete and/or partial dentures, dental appliances, and dental prostheses devices, including gaskets for over dentures, splints, night guards and sleep apnea anti-snore devices, and other devices as prescribed.

G. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

To the submitter's knowledge, there are no technological characteristic differences between the submitted devices, **TALON® and REVERE®** and the predicate devices, **Comfor-dent Denture Liner, K910795 and Comfort Acrylics Pliable Denture Liners and Splints, K900799**.

TABLE OF DIFFERENCES BETWEEN
TALON and REVERE and the PREDICATE DEVICE(S)

Characteristic	TALON®	REVERE®	Comfor-Dent Denture Liner, K910795	Comfort Acrylics Pliable Denture Liners & Splints, K900799
Thermoplastic moldable acrylic	YES	YES	YES	YES
Used for fabrication, repair and relining of dentures, dental appliances and dental prostheses devices	YES	YES	YES	YES
Excellent bond to methacrylates	YES	YES	YES	YES
Premixed for immediate use and safety	YES	YES	YES	YES
Repairable	YES	YES	YES	YES
Two (2) hour curing time at 155°F	YES	YES	YES	YES
Will no leach out of plasticizers into the oral cavity	YES	YES	YES	YES
Can be processed in the ½ denture flask method	YES	YES	YES	YES
Can be laminated without the use of adhesives or bonding agents	YES	YES	YES	YES
Has a "memory" and will not warp under normal wear and handling procedures	YES	YES	YES	YES
Gas chromatographic studies verify a residual monomer level of up to 0.14%	YES	YES	YES	YES
Shore-D hardness testing shows it will not harden over time under normal wear and handling conditions	YES	YES	YES	YES
Eliminates undercut wax-out	YES	YES	YES	YES
Includes a customer specified colorant	NO	YES	NO	NO

H. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW - as required by 807.92(b)(1)

SUMMARY:

Predicate devices:

Comfort Acrylics Company (now Comfort Acrylics Company, Inc.) is the owner of the predicate devices. The submitter, Mr. Watson, directed performance testing and validation of the submitted devices initially submitted in January, 1990, with FDA authorization to market the devices initially dated May 15, 1990, coupled with follow up submissions, throughout 1990 and continued FDA authorization to market the devices continued throughout 1991, with 510(k)'s K910795 and K900799. In July, 1998 a submission in reference to the addition of a colorant to the above submissions trademarked as Revere® was submitted to FDA, with a Substantial Equivalence letter from FDA dated August 19, 1998 subsequently received.

Submitted devices:

Submitter claims that the predicate devices and the submitted devices are manufactured, under existing executed agreements, to patent specifications [the patent is owned by the submitter] and detailed in those executed agreements between the submitter and **Comfort Acrylics Company** (now Comfort Acrylics Company, Inc.) the owner of the predicate devices.

Non-Clinical Testing

The submitted devices have undergone significant verification and validation testing. Validation testing included testing of **Talon® and/or Revere®** manufacturing processes at the University of Washington Chemistry Department during the development of **Talon®** by Sherman L. Watson, with verified testing results completed through Gas Chromatographic studies performed by Cyro Industries of Orange, Connecticut, which indicated a 0.14% unreacted monomer immediately following polymerization. Their conclusion indicated this is a very low number in polymer chemistry and very satisfactory for uses in dentistry.

Shore-D hardness testing was performed by Braun-Intertec of Portland, Oregon of TMJ/D appliances after 1 year of continuous use, compared to a new appliance, yielded identical results indicating no change of hardness over time. No loss of resiliency, nor retention have ever been reported.

Consultation with Dr. Frances Storrs, MD, a dermatologist at Oregon Health Sciences University in Portland, Oregon whose area of research is contact dermatitis of acrylics, stated in her opinion I could not have selected a safer acrylic.

The performance data records documents that **TALON®** and **REVERE®** met their stated requirements and design specifications as intended.

Biocompatibility Data

Finally, the submitter contracted with a qualified testing laboratory, **NAMSA, 9 Morgan, Irvine, California 92618**, to perform biocompatibility testing on the finished device in the form intended to be used and to come in contact with a patient using an appropriate dental device. The biocompatibility testing was performed utilizing samples of REVERE® which is exactly the same as TALON® except of the addition of a specified colorant.

The tests performed included:

1. Cytotoxicity Study Using the ISO Elution Method, (1X MEM Extract)
2. ISO Maximization Sensitization Study – Extract in 0.9% sodium chloride USP
3. ISO Maximization Sensitization Study – Extract in sesame oil, NF (SO)
4. ISO Vaginal Irritation Study - Extract in 0.9% sodium chloride USP
5. ISO Vaginal Irritation Study - Extract in sesame oil, NF (SO)
6. ISO Skin Irritation Study

The test results indicated [based on the above list]:

1. No evidence of causing cell lysis or toxicity
2. The SC test article extract showed no evidence of causing delayed dermal contact sensitization in the guinea pig
3. The SO test article extract showed no evidence of causing delayed dermal contact sensitization in the guinea pig
4. The SC test article extract would be considered a nonirritant to the vaginal mucosal tissue of the rabbit
5. The SO test article extract would be considered a nonirritant to the vaginal mucosal tissue of the rabbit
6. No erytherma and no edema were observed on the skin of the rabbits. The Primary Irritation Index for the test article as calculated to be 0.0. The response to the test article was categorized as negligible.

The results of this biocompatibility data confirms that **TALON®** and **REVERE®** met its requirements, design specifications, and has been determined by the above named laboratory to be "biocompatible" as intended.

The submitter believes that the predicate devices, **Comfor-Dent Denture, K910795** and **Comfort Acrylics Pliable Denture Liners and Splints, K90079's** 510(k) submission did NOT include summaries of non-clinical testing data and biocompatibility testing data.

The submitter believes **Talon Acrylics Inc.**'s submitted **TALON** and **REVERE**'s summary of non-clinical testing and biocompatibility testing data further documents the submitter's claim of substantial equivalence.

I. SUBSTANTIAL EQUIVALENCE SUMMARY

The submitted devices, **TALON®** and **REVERE®**, have the same indications for use as the predicate device(s), **Comfor-dent Denture, K910795** and **Comfort Acrylics Pliable Denture Liners and Splints, K900799.**

TALON® and **REVERE®** both have the same or very similar technological characteristics as the predicate device(s). However, while the submitter believes the characteristics are sufficiently precise to assure equivalence, the submitter has carried out validation, biocompatibility testing in compliance with **807.92(b)(2)**, and performance testing to further document substantial equivalence. The results of this testing substantiates that **TALON®** and **REVERE®** performs the same results as the predicate devices.

J. CONCLUSIONS:

The device characteristics, performance testing and biocompatibility testing data document that **TALON®** and **REVERE®** devices are substantially equivalent to the predicates **Comfor-dent Denture, K910795** and **Comfort Acrylics Pliable Denture Liners and Splints, K900799**, which are registered as my **Talon®** Thermoplastic Acrylic Elastomer Polymers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2007

Mr. Sherman Watson
President
Talon Acrylics, Incorporated
850 N.E. 102nd Avenue
Portland, Oregon 97220

Re: K071245
Trade/Device Name: TALON and REVERE
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: July 03, 2007
Received: July 06, 2007

Dear Mr. Watson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071245

Device Names: **TALON and REVERE**

Indications for Use:

TALON and REVERE are a moldable acrylic compound for use in the fabrication, of TMJ/D Splints / Night Guards / Anti-Bruxism Guards / Mouth Guards / Sleep Apnea Anti-Snore Appliances / Liners, and/or Relines for Complete and Partial Dentures / Gaskets for Overdentures / and other dental prostheses device appliances as prescribed.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulley for HSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071245